THERAFLU SEVERE COLD RELIEF COMBO PACK- acetaminophen, dextromethorphan hbr, diphenhydramine hcl
Haleon US Holdings LLC

Drug Facts

Active Ingredients (in each packet) **(Daytime)**

Acetaminophen 500 mg

Dextromethorphan HBr 20 mg

Purposes **(Daytime)**

Pain reliever/Fever reducer

Cough suppressant

Active ingredients (in each packet) **(Nighttime)**

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Purposes **(Nighttime)**

Pain reliever/Fever reducer

Antihistamine/Cough suppressant

Uses **(Daytime)**

• temporarily relieves these symptoms due to a cold:

  • minor aches and pains • minor sore throat pain • headache
  • cough due to minor throat and bronchial irritation

• temporarily reduces fever

Uses **(Nighttime)**

• temporarily relieves these symptoms due to a cold:

  • minor aches and pains • minor sore throat pain
  • headache • runny nose
  • sneezing • itchy nose or throat
  • itchy, watery eyes due to hay fever
  • cough due to minor throat and bronchial irritation

• temporarily reduces fever

Warnings (Daytime)

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

• more than 4,000 mg of acetaminophen in 24 hours • with other drugs containing acetaminophen

• 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

• skin reddening • blisters • rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting consult a doctor promptly.

Do not use

• in a child under 12 years of age • if you are allergic to acetaminophen

• with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

• if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson’s disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

• liver disease

• cough that occurs with too much phlegm (mucus)

• cough that lasts or is chronic such as occurs with smoking, asthma or emphysema

Ask a doctor or pharmacist before use if you are

• taking the blood thinning drug warfarin

Stop use and ask a doctor if

• fever gets worse or lasts more than 3 days

• redness or swelling is present

• new symptoms occur

• pain or cough gets worse or lasts more than 7 days

• cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Warnings **(Nighttime)**

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

• more than 4,000 mg of acetaminophen in 24 hours

• with other drugs containing acetaminophen

• 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions.

Symptoms may include:

• skin reddening • blisters • rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting consult a doctor promptly.

Do not use

• in a child under 12 years of age

• if you are allergic to acetaminophen

• with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

• with any other product containing diphenhydramine, even one used on the skin

• if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson’s disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

• liver disease • glaucoma

• trouble urinating due to an enlarged prostate gland

• a breathing problem such as emphysema or chronic bronchitis

• cough that occurs with too much phlegm (mucus)

• cough that lasts or is chronic such as occurs with smoking, asthma or emphysema

Ask a doctor or pharmacist before use if you are

• taking sedatives or tranquilizers

• taking the blood thinning drug warfarin

When using this product

• avoid alcoholic drinks

• marked drowsiness may occur

• alcohol, sedatives and tranquilizers may increase drowsiness

• be careful when driving a motor vehicle or operating machinery

• excitability may occur, especially in children

Stop use and ask a doctor if

• fever gets worse or lasts more than 3 days • redness or swelling is present

• new symptoms occur • cough comes back or occurs with rash or headache that lasts

• pain or cough gets worse or lasts more than 7 days

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions **(Daytime)**

• do not use more than directed

• take every 4 hours, while symptoms persist. Do not take more than 6 packets in 24 hours unless directed by a doctor.

Age	Dose
adults and children 12 years of age and over	one packet
children under 12 years of age	do not use

• dissolve contents of one packet into 8 oz. hot water; sip while hot. Consume entire

drink within 10-15 minutes.

• if using a microwave, add contents of one packet to 8 oz. of cool water; stir briskly before and after heating. Do not overheat.

Directions **(Nighttime)**

• do not use more than directed

• take every 4 hours, while symptoms persist. Do not take more than 5 packets in 24 hours unless directed by a doctor.

Age	Dose
adults and children 12 years of age and over	one packet
children under 12 years of age	do not use

• dissolve contents of one packet into 8 oz. hot water; sip while hot. Consume entire drink within 10-15 minutes.

• if using a microwave, add contents of one packet to 8 oz. of cool water; stir briskly before and after heating.

Do not overheat.

Other information **(Daytime)**

• each packet contains: potassium 10 mg, sodium 20 mg

• phenylketonurics: contains phenylalanine 20 mg per packet

• store at controlled room temperature 20-25°C (68-77°F). Protect product from heat and moisture.

Other information **(Nighttime)**

• each packet contains: potassium 10 mg, sodium 23 mg

• phenylketonurics: contains phenylalanine 13 mg per packet

• store at controlled room temperature 20-25°C (68-77°F). Protect product from heat and moisture.

Inactive ingredients **(Daytime)**

acesulfame potassium, anhydrous citric acid, aspartame, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, maltodextrin, natural and artificial flavors, silicon dioxide, sodium citrate, soy lecithin, sucrose, tribasic calcium phosphate

Inactive Ingredients (Nighttime)

acesulfame potassium, anhydrous citric acid, aspartame, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, maltodextrin, natural and artificial flavors, silicon dioxide, sodium citrate, soy lecithin, sucrose, tribasic calcium phosphate

Questions or comments? **(Daytime)**

1-855-328-5259

Questions or comments? **(Nighttime)**

1-855-328-5259

Other Information

DO NOT TAKE THE THERAFLU SEVERE COLD RELIEF DAYTIME AND THERAFLU SEVERE COLD RELIEF NIGHTTIME PRODUCTS AT THE SAME TIME.
DO NOT TAKE MORE THAN 5 DOSES IN TOTAL IN ANY 24 HOUR PERIOD.

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE.
KEEP CARTON FOR REFERENCE. DO NOT DISCARD.

DO NOT TAKE THE THERAFLU SEVERE COLD RELIEF DAYTIME AND THERAFLU SEVERE COLD RELIEF NIGHTTIME PRODUCTS AT THE SAME TIME.
DO NOT TAKE MORE THAN 5 DOSES IN TOTAL IN ANY 24 HOUR PERIOD.

DO NOT TAKE A DOSE OF THE SEVERE COLD RELIEF NIGHTTIME PRODUCT SOONER THAN 4 HOURS AFTER THE LAST DOSE OF SEVERE COLD RELIEF DAYTIME PRODUCT UNLESS DIRECTED BY YOUR DOCTOR.

TAMPER EVIDENT INNER UNIT
DO NOT USE IF SEALED THERAFLU PACKET IS TORN OR BROKEN

1-855-328-5259

Distributed by: Haleon, Warren, NJ 07059

207735

Package/Label Principal Display Panel

MULTI-SYMPTOM **COLD RELIEF**

NEW FORMULA

THERAFLU

SEVERE

COLD RELIEF

MULTI-SYMPTOM COLD RELIEF

***Hot liquid therapy* that relieves:**

/Cough /Sore throat pain /Head and body ache

/Fever /Runny nose (Nighttime only)

/Sneezing (Nighttime only)

Honey Lemon Flavor

USE AS DIRECTED

DAYTIME

Acetaminophen Pain Reliever/Fever Reducer

Dextromethorphan HBr Cough suppressant

NIGHTTIME

Acetaminophen Pain Reliever/Fever Reducer

Diphenhydramine HCl Antihistamine/Cough Suppressant

DAYTIME

18 PACKETS

24 TOTAL PACKETS

NIGHTTIME

6 PACKETS

THERAFLU SEVERE COLD RELIEF COMBO PACK

acetaminophen, dextromethorphan hbr, diphenhydramine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-0123

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-0123-01	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	06/01/2024	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	3 PACKET	3
Part 2	1 PACKET	1

Part 1 of 2

THERAFLU SEVERE COLD RELIEF DAYTIME

acetaminophen, dextromethorphan hbr powder, for solution

Product Information	
Item Code (Source)	NDC:0067-0100
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SOYBEAN LECITHIN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics			
Color	WHITE ((to off white, yellow, and brown))	**Score**	
Shape		**Size**	
Flavor	HONEY (Lemon)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0067-0100-06	6 in 1 CARTON		

1		1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/01/2023	

Part 2 of 2

THERAFLU SEVERE COLD RELIEF NIGHTTIME

acetaminophen, diphenhydramine hcl powder, for solution

Product Information

Item Code (Source)	NDC:0067-0101
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SOYBEAN LECITHIN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color	WHITE ((to off white, yellow, and brown))	**Score**	
Shape		**Size**	
Flavor	HONEY (Lemon)	**Imprint Code**	

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-0101-06	6 in 1 CARTON		
1		1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/01/2024	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 6/2024 Haleon US Holdings LLC